REMARKS

The Advisory Action mailed November 18, 2002, has been received and reviewed. Claims 1-5 and 20-24 are pending in the application and stand rejected. This amendment is submitted with a Request for Continued Examination under 37 C.F.R. § 1.114. Claims 1 and 2 have been amended as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Rejections Withdrawn

The amendments to claims 1 and 2 filed November 4, 2002, were entered by the Examiner. In view of the amendments, the rejections of claims 1-5 and 20-24 under 35 U.S.C. § 112, first paragraph, for lack of written description, the rejections of claims 1-5 and 20-24 under U.S.C. § 112, second paragraph, as being indefinite, and the rejections of claims 1-5 and 20-24 under U.S.C. § 102(b) as being anticipated by Haan et al. were withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

The rejections of claims 1-5 and 20-24 were maintained under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement. Claims 1 and 2 have been amended as set forth herein. In view of the amendments, applicants respectfully traverse the rejections.

Specifically, it was thought that the specification does not teach how to make and use any peptide or any immunogenic polypeptide "having up to 15 amino acids" comprising the sequence VLXDDLLEA of SEQ ID NO: 1 since the term "comprising" is open-ended. It was further asserted that given the indefinite number and type of amino acids in addition to those recited in SEQ ID NO: 1 that may be present on the claimed polypeptides, that it is unpredictable which undisclosed peptide or immunogenic polypeptide would have the same structure and function as the polypeptide of SEQ ID NO: 1.

Although applicants do not agree that the claims are not enabled, claims 1 and 2 have been amended to recite a peptide or an immunogenic polypeptide, respectively, "having 9 amino acids... having the sequence VLXDDLLEA (SEQ ID NO: 1)." Since the specification is

enabled for the peptide and immunogenic polypeptide having 9 amino acids of SEQ ID NO: 1, the claims should be considered enabled.

With regard to the assertion that the specification does not provide enablement for any "vaccine" or any "pharmaceutical formulation" against Graft versus host disease treating HA-1 related autoimmune disease, the amendments to claims 1 and 2 should obviate the assertion. The amended claims are directed to a peptide or immunogenic polypeptide of SEQ ID NO: 1 and not to any peptide or any polypeptide comprising SEQ ID NO: 1. Accordingly, the vaccine and pharmaceutical composition claims should be enabled.

With further regard to dependent claims 5, 23 and 24, they are directed to pharmaceutical formulations including the peptide or immunogenic polypeptide of claim 1 or 2. As stated in the as filed specification "[t]he invention provides a (poly) peptide which can be functionally presented to the immune system." (Specification as filed, page 6, lines 24-25). One of ordinary skill in the art would be able to produce a pharmaceutical formulation, which may comprise saline, that includes the claimed peptide or immunogenic polypeptide without undue experimentation, such that the peptide or immunogenic polypeptide are functionally presented to the immune system.

Regarding dependent claims 4, 21 and 22, they have been amended to recite in part "a preparation for stimulating the immune response" including the peptide or immunogenic polypeptide of claim 1 or 2. The disclosure of the as filed specification recites "[f]or tolerance induction very small doses [of peptides of the present invention] can be given repeatedly, for instance intravenously, but other routes of administration may very well be suitable too." (Specification as filed, page 7, lines 22-24). Since it is well known that peptides can simulate an immune response when intravenously administered to a subject, one of ordinary skill in the art would be able to produce a preparation that simulates an immune response using the peptide and immunogenic peptide of claims 1 and 2 without undue experimentation.

Accordingly, applicants request reconsideration and withdrawal of the enablement rejections of independent claims 1 and 2, and claims 4, 5 and 20-24 depending therefrom.

CONCLUSION

In view of the amendments and remarks presented herein, applicants respectfully submit that the amended claims define patentable subject matter. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE

1. (Four times amended) A peptide having [up to 15] 9 amino acids constituting a T-cell epitope obtainable from the minor Histocompatibility antigen HA-1, said peptide [comprising] having the sequence VLXDDLLEA (SEQ ID NO:1), wherein X represents a histidine or an arginine residue.

2. (Four times amended) An immunogenic polypeptide having [up to 15] 9 amino acids obtainable from the minor Histocompatibility antigen HA-1, said immunogenic polypeptide [comprising] having the sequence VLXDDLLEA (SEQ ID NO:1), wherein X represents a histidine or an arginine residue.

4. (Twice amended) A [vaccine] preparation for stimulating the immune response comprising the immunogenic polypeptide of claim 2.

21. (Amended) A [vaccine] preparation for stimulating the immune response comprising the peptide of claim 1.

22. (Amended) The [vaccine] preparation for stimulating the immune response of claim 4 wherein X is a histidine residue.